K122643

JAN 07 2013

510(k) Summary

Date:	November 8, 2012
Submitter:	Midmark Corporation 675 Heathrow Drive Lincolnshire, IL 60069 USA
Contact Person:	Mark Greenwood Director, Engineering and Product Development (847) 415-9800
Device Name:	Vantage Panoramic X-Ray System
Classification Name:	System, x-ray, extraoral source, digital (21 CFR 872.1800, Product Code MUH)
Predicate Devices:	Instrumentarium Orthopantomograph OP200D (K043612) Planmeca ProMax (K011619)
Description of Device:	The Progeny Vantage Panoramic X-Ray System is an extraoral radiographic imaging system for producing digital radiographs in panoramic and cephalometric views of the teeth, jaw and oral structure. The Progeny Vantage Panoramic Extraoral Radiographic Imaging System consists of the following main components: X-ray tubehead with integrated collimation Digital Image Receptor Rotating C-Arm for tubehead and image receptor mounting Overhead Arm Elevating Column Patient Positioning Table Electronic Control Unit Computer Display Workstation 8 ft. coil cord with exposure switch Optional cephalometric extension arm
Intended Use:	The intended use of the Progeny Vantage Extra Oral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric

radiographic examinations for use in orthodontic treatment planning and evaluation.

Substantial Equivalence Comparison:

Technical Characteristic	Progeny Vantage	Instrumentarium OP200D	Planmeca ProMax
kVp	60-84 kVp	57-85 kVp	50-84 kVp
mA	4-14 mA	2-16 mA	.5-16 mA
Sensor type	CCD	CCD	CCD
Image Pixel size	96 um	96 um	66, 99, or 132 um
Panoramic Scan Time	2.5-16s	2.7-14s	2.7-16s
X-Ray tube focal spot	0.5mm	0.5mm	0.5mm
Ceph option	Yes	Yes	Yes

Intended Use for Each Device:

Progeny Vantage: The intended use of the Progeny Vantage Extra Oral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation.

Instrumentarium OP200D: Orthopantomograph OP200 (film unit) and OP200D (digital unit) devices are intended to be used for producing x-ray radiographs of dentition, TM-joints, and other oral structures. The units are capable of taking panoramic, TM-joint, maxillary sinus radiographs from patients. When the units are equipped with cephalometric option Orthoceph OC200 (film unit) and OC200D (digital unit) units can be used for cephalometric radiography and examinations related thereto. OP200 or OC200 units can also be equipped with Ortho Trans (OT) option, which is capable of taking both cross and longitudinal slices of region of interest. Ortho Trans uses linear tomography imaging principle.

Planmeca ProMax: The ProMax, Panoramic X-Ray Imaging System with Cephalostat, is an extraoral source X-Ray System, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. The device can be equipped with accessories to fulfill different diagnostic needs. In digital configuration the images are

	displayed on a monitor, and image manipulation, archiving, and communication are performed via a computer.
Technical Analysis:	A review of the technical characteristics indicates no significant differences between the Vantage unit and the predicate devices. The radiographic technique factors which would determine patient radiation dosage are almost identical. In fact, many of the key components (x-ray tubes, detectors, etc) are sourced from the same suppliers. The intended uses of the Vantage unit and the predicate devices also have no significant differences. All three devices' intended use focuses on providing radiograph examination of the teeth, jaw, and oral structures. The Progeny Vantage and Instrumentarium IFU statements specifically describe cephalometric while the Planmeca refers to more general "different diagnostic needs." The Instrumentarium unit IFU describes a linear tomography feature which is NOT present in Vantage unit or IFU and therefore should not be considered.
Non-Clinical Tests:	The Progeny Vantage Panoramic unit was tested per IEC 61223-3-4 which is an FDA recognized standard for acceptance testing of dental x-ray equipment, specifically Section 7 which is for Cephalometric equipment. The Progeny Vantage with ceph option passed this testing which is a confirmation that the product is safe and effective.
Clinical Tests:	Two licensed dentists reviewed images taken of a skull phantom with the Progeny Vantage with Ceph. Both dentists deemed that the image quality was acceptable and that they would be effective as effective as cephalometric images. In addition, the two dentists reviewed images taken of the skull by the Instrumentarium OP200D of the skull phantom and Planmeca sample cephalometric images and concluded that the Progeny Vantage images were at least as effective as the Instrumentarium and Planmeca images.
Conclusion:	The Vantage Panoramic X-Ray system is substantially equivalent to other legally marketed devices in the United States. Specifically, the Vantage Panoramic X-Ray system is substantially equivalent in technical characteristics, intended use, and effectiveness to the OP200D marketed by Instrumentarium and the ProMax marketed by Planmeca.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Progeny Dental, *A Midmark Company*
Mr. Mark Greenwood
Director, Engineering and Product Development
675 Heathrow Drive
LINCOLNSHIRE IL 60069

January 7, 2013

Re: K122643
Trade/Device Name: Progeny Vantage Panoramic X-Ray System
Regulation Number: 21 CFR §872.1800
Regulation Name: System, x-ray, extraoral source, digital
Regulatory Class: II
Product Code: MUH
Dated: December 19, 2012
Received: December 26, 2012

Dear Mr. Greenwood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122643

Device Name: Progeny Vantage Panoramic X-Ray System

Indications For Use:

The indications for use of the Progeny Vantage Panoramic X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K122643